STATE OF CONNECTICUT

DEPARTMENT OF AGRICULTURE

Steven K. Reviczky, Commissioner

DEPARTMENT OF AGRICULTURE
CTGrown.gov

TESTIMONY BEFORE THE ENVIRONMENT COMMITTEE

Proposed Senate Bill No. 287

An Act Authorizing the Testing Of Shellfish at Alternative Lab Facilities

The Department of Agriculture is opposed to Senate Bill #287. This bill proposes that the Department of Public Health, in consultation with the Department of Agriculture, prepare a report on the status of authorizing additional laboratories to perform testing of shellfish.

On 6/30/15 the Governor signed AN ACT IMPLEMENTING PROVISIONS OF THE STATE BUDGET FOR THE BIENNIUM ENDING JUNE 30, 2017 CONCERNING GENERAL GOVERNMENT, EDUCATION AND HEALTH AND HUMAN SERVICES. In Section 118 of the bill the Department of Agriculture was tasked with reporting to the Environment Committee on the need for and the viability of establishing a laboratory east of the Connecticut River for testing shellfish. The report is included for your review.

After considerable analysis it was concluded that the existing State Department of Agriculture's Aquaculture Laboratory facility in Milford is adequate to perform testing for the state's shellfish industry.

A guide to the report is as follows:

A) A description of the requisite laboratory testing for shellfish as prescribed by the Department of Agriculture, federal law and any other provisions of law. **Section 1**
B) An explanation of the standards that such laboratory is required to meet. **Section 2**
C) A description of any requisite equipment and facilities required to perform such testing. **Section 3**
D) A listing of the qualifications that any person who performs such testing is required to possess. **Section 4**
E) An assessment of the adequacy of existing state facilities to perform such testing for the state's shellfish industry. **Section 5**
F) The volume of such testing that could occur at additional laboratories and identification of any existing private owned facilities, state resources or state facilities that could adequately and appropriately provide locations for such testing, including but not limited to, **Section 6**
   A cost-benefit analysis for modifying any such existing state resources nor facilities to provide such testing. **Section 6 (2), Scenarios 1-3.**
G) Summary of Findings
H) Exhibits

860-713-2501
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165 Capitol Avenue, Hartford, CT 06106

A report concerning the need for and viability of establishing a laboratory located east of the Connecticut River for the testing of shellfish.

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Section 118 Implementer Bill Requiring the Commissioner of Agriculture to Report to the Environment Committee: Report on the need for and viability of establishing a laboratory east of the Connecticut River for testing shellfish.

Background:

Shellfish are filter-feeding organisms that pump large quantities of seawater through their bodies as a part of the normal feeding process. As a result any microorganisms, including human pathogens, present in the growing area can become concentrated in shellfish meats by as much as 100 times that found in the water column. Sewage contamination is the main source of human pathogens in shellfish growing waters and the correlation between sewage pollution and disease has been demonstrated. In order to ensure the safety of shellfish for human consumption, shellfish growing areas are classified based on evidence of contamination[i].

The DA/BA uses the guidelines and standards set forth by the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish 2013 Revision Model Ordinance (NSSP-MO) to classify Connecticut's shellfish growing areas. The NSSP is a Federal/State cooperative program, recognized by the United States Food and Drug Administration (USFDA) and the Interstate Shellfish Sanitation Conference (ISSC), for the sanitary control of shellfish produced and sold for human consumption. Growing area classifications are based on evidence of contamination found through the shoreline survey and are reevaluated on an annual basis. The sanitary survey includes the identification of actual and potential sources of pollution that may adversely impact the growing area, an evaluation of meteorological and hydrographic factors, and an assessment of water quality.

These standards are applied to all shellfish growing areas in Connecticut coastal waters, overlying beds managed by either the state or the municipality which may be utilized for recreational or commercial shellfishing activities. These standards were developed to prevent illnesses associated with the consumption of raw shellfish and are applied to both recreational and commercial categories of shellfish harvest, and the majority of recreational beds are intermingled with commercial shellfish beds.

The majority of shellfish growing areas in Connecticut are highly susceptible to water quality impacts related to the highly developed nature of our coastal areas, particularly those related to sewage treatment infrastructure and storm water runoff, and are managed on a Conditionally Approved basis. The requirements for managing Conditional Approved shellfish growing areas are extensive and require a significant investment in time and resources at both the State and Municipal level. In order to ensure the protection of public health associated with the consumption of shellfish from these highly impacted coastal waters, shellfish growing area management, water and shellfish sampling, and pollution source monitoring are far more extensive than that required for the management of less developed coastal areas.

1. **A description of the required laboratory testing for shellfish under the minimum guidelines of the National Shellfish Sanitation Program Model Ordinance (NSSP-MO).**

The National Shellfish Sanitation Program (NSSP) approved methods of laboratory tests are described in Table 1. The DABA laboratory uses the following approved NSSP microbiological testing methods; APHA Decimal dilution – MPN for fecal coliform indicator in seawater and shellfish and the mTEC method for fecal coliform indicator in sewage and seawater. The method of Modified Double Agar Overlay (MDAO) is used for determining male-specific coliphage (MSC) in sewage and shellfish. The APHA Mouse Bioassay method is used for marine biotoxin testing. The MPN enrichment/PCR procedure for total and pathogenic Vp method is used for vibrio enumeration for *Vibrio parahaemolyticus*. Also included in Table 1 are the time required for processing for each of these analyses.

Table 1. Types of Analyses performed at Bureau of Aquaculture laboratory in Milford, including the total processing time in hours required for each type of analysis.

Type of Analysis	Matrix	Time for Processing (Approx)
Fecal Coliform mTEC	Seawater	24 hours
Fecal Coliform MPN	Shellfish Tissue	48 hours
Total and Pathogenic *Vibrio parahaemolyticus MPN/PCR*	Shellfish Tissue	50 hours
Paralytic Shellfish Poison (PSP) APHA	Shellfish Tissue	28 hours
Male Specific Coliphage (MSC) MDAO	Sewage, Seawater, Tissue	18 to 20 hours

According to the NSSP, shellfish growing areas may be classified as Approved (A), Conditionally Approved (CA), Conditionally Restricted (CRR), Restricted (R), or Prohibited (P). Minimum sampling requirements vary depending on the water quality classification associated with each growing area, and are summarized in Table 2 below. In addition, after a sewage or rainfall closure event, additional tissue and water samples are required to reopen the areas; the need for reopening samples is determined by rainfall or other closure events and the number of samples cannot be predicted and is not included in the table below. The type of analysis required to reopen the areas depends on the cause of the closure; routine rainfall closures require water and tissue samples to reopen, while sewage closures may require additional viral testing for MSC to ensure that the shellfish are no longer contaminated.

Table 2. Sampling Requirements for each sampling station by Growing Area Classification. APC indicates "Adverse Pollution Condition" of rainfall, tide, river stage, etc.

Classification of Area	Number of APC Samples per Year	Number of Conditionally Approved Open Samples	Reopening Samples Required?	Type of Samples Required
Approved (A)	5	NA	Yes: Water and Tissue after sewage bypass/3" rain event	Water Tissue
Conditionally Approved	5	12 for year-round	Yes: After each	Water

Classification of Area	Number of APC Samples per Year	Number of Conditionally Approved Open Samples	Reopening Samples Required?	Type of Samples Required
(CA)		areas 7 for seasonal areas	closure event	Tissue
Conditionally Restricted/Seasonal (CRR)	5	7	Yes: prior to seasonal reopening	Water
Restricted (R)	5	NA	NO	Water Tissue for Relay
Prohibited (P)	5	NA	NO	Water

Each coastal town in Connecticut has a number of sampling stations that are located to adequately assess each classified growing area. The number of water quality monitoring station organized by town and growing area classification is provided in Table 3. There are 542 classified sampling stations maintained by the DA/BA that are used in order to evaluate each growing area for compliance with the national program water quality standards. Several municipalities maintain shellfish commissions which have agreed to take on certain responsibilities for sample collection in certain growing areas. This information is also provided in Table 3. In order to arrive at the total number of samples required on an annual basis to maintain compliance with the NSSP shellfish growing area program, the number of samples in each classification is multiplied by the minimum sample requirements for each classification. *Please note that these calculations include **only the minimum number of samples required to maintain growing area classifications**; this total does not include the unpredictable and variable number of samples required to assess impacts after sewage or rainfall events in order to reopen areas.*

Table 3. Sampling stations by municipality and growing area classification. Shellfish commissions in certain municipalities are responsible for collecting the conditionally approved area samples (monthly open and reopening) and certain approved samples.

		Growing Area Classification Code					
Municipality	Shellfish Commission Sampling Responsibility?	A	CA	CRR	P	RR	Grand Total by Town
GREENWICH	Yes	12	12	4		7	35
STAMFORD	No	12		2		11	25
DARIEN	No	9	6	1		2	18
NORWALK	No	5	24	3	1	1	34
WESTPORT	No	12	16	1		6	35
FAIRFIELD	No		9	3	2	3	17
BRIDGEPORT	No				1	9	10
STRATFORD	No		3			5	8
MILFORD	No	21	12			7	40
WEST HAVEN	No		6			7	13
NEW HAVEN	No		2			4	6

		Growing Area Classification Code					
Municipality	Shellfish Commission Sampling Responsibility?	A	CA	CRR	P	RR	Grand Total by Town
EAST HAVEN	No		6			1	7
BRANFORD	No	14	15	2		8	39
GUILFORD	Yes	9	27	4	1	4	45
MADISON	Yes	3	10			11	24
CLINTON	No			5		10	15
WESTBROOK	No				5	8	13
OLD SAYBROOK	No					18	18
OLD LYME	No					17	17
EAST LYME	Yes		13			9	22
WATERFORD	Yes		19	1			20
NEW LONDON	No				2	3	5
GROTON	Yes/No (DABA Area A, 10 samples)	4	24	2	3	8	41
STONINGTON	Yes	13	14	2	3	3	35
Grand Total # Stations by Classification		114	218	30	18	162	542
Minimum # Samples per Year Required by Classification Type		5	12	7	5	5	
Minimum Total # Samples Required Per Year		**570**	**2616**	**210**	**90**	**810**	**4296**

Based on these calculations, the minimum number of samples required to maintain shellfish growing area classifications for the entire state is **4296** seawater samples. Based on the 2014 sample totals by each type of analysis, an additional **2354** seawater and **143** shellfish tissue samples were collected for reopening and relay verification, **130** phytoplankton, **14** paralytic shellfish toxin, **85** *Vibrio parahaemolyticus* and **104** male specific coliphage samples were analyzed at the Milford laboratory (Table 4).

In Connecticut, all of these sample analyses are performed by trained Microbiologist staff at the DA/BA laboratory at 190 Rogers Ave. Milford. The Department of Public Health (DPH) Katherine A. Kelley State Public Health Laboratory at 395 West Street Rocky Hill also serves as a backup for the Milford laboratory for seawater samples collected for mTEC fecal coliform analysis only, and depending on the year, may process up to 250 seawater samples per year for municipal shellfish programs.

Table 4. Number and Types of Samples Analyzed by the Bureau of Aquaculture Laboratory in Milford.

Year	Seawater Fecal Coliform	Phytoplankton Samples	Paralytic Shellfish Poison (PSP)	Shellfish Tissue Fecal Coliform	Total and Pathogenic Vibrio parahaemolyticus	Male Specific Coliphage
2013	6500	113	14	133	16	67
2014	6650	130	14	143	85	104
2015	6957	193	35	125	193	102

2. Explanation of the standards a shellfish testing laboratory must meet:

The NSSP Model Ordinance describes in detail the procedures that must be followed in order to designate a laboratory as an "NSSP Laboratory" for the purpose of providing analytical support to a state shellfish sanitation program. The DA/BA in its role as the State Shellfish Authority must ensure compliance with Chapter III of the current NSSP *Guide for the Control of Molluscan Shellfish* as follows:

- All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.
- The NSSP Laboratory must have qualified, adequately trained staff with appropriate, calibrated equipment and workspace sufficient to conduct the numbers and types of daily/weekly/monthly analyses anticipated.
- The Authority shall ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results;

The specific NSSP and DA/BA requirements may be found attached as Exhibits 1 through 4:

Exhibit 1: NSSP Guide for the Control of Molluscan Shellfish 2013 Revision. Section II. Chapter III. Laboratory @.01 Quality Assurance. A – F

Exhibit 2: NSSP Guide for the Control of Molluscan Shellfish 2013 Revision. Section II. Chapter III. Laboratory @.02 Methods

Exhibit 3A: NSSP Section IV. Guidance Documents. Chapter II. Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers

Exhibit 3B: NSSP Section IV. Guidance Documents. Chapter II. Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers: Laboratory Evaluation Checklists

Exhibit 4: Connecticut Department of Agriculture Bureau of Aquaculture Standard Operating Procedures for Designating Laboratories as NSSP Laboratories for the Purpose of Providing Analytical Support to a State Shellfish Sanitation Program

3. **A description of any equipment and facilities required to perform the testing:**

The equipment list found in Exhibit 5 will enable a laboratory to process shellfish meats and seawaters for the following NSSP microbiological testing methods; APHA decimal dilution – MPN for fecal coliform indicator in seawater and shellfish and the mTEC method for fecal coliform indicator in seawater.

Based on the most current equipment quotes provided by the approved State of Connecticut vendor Fisher Scientific, the total cost to equip a newly established laboratory is **$218,603.**

A laboratory facility will need a minimum of 1500 square feet. The space will comprise 300 square feet of office administrative area and 1200 square feet of laboratory space consisting of benches, counters, work area, and sinks. Within the 1200 laboratory space, a minimum of 300 square feet must be a dedicated room constructed for the autoclave and glass washing machine, which generate significant amounts of heat. These laboratory space requirements do not include restroom or break facilities which would require additional square footage.

4. **The qualifications any person who performs the testing must possess.**

The minimum qualifications required by the State of Connecticut Department of Administrative Services for a Microbiologist 1.

Exhibit 6. State of Connecticut Department of Administrative Services Exam Announcement Microbiologist I.

KNOWLEDGE, SKILL AND ABILITY:

- Knowledge of current principles and practices of biomedical sciences and microbiological disciplines including bacteriology, parasitology, virology and others as they relate to public health;
- knowledge of equipment and instruments used in modern public health laboratories;
- knowledge of applicable analytical techniques;
- knowledge of quality assurance and quality control policies and procedures; knowledge of universal laboratory precautions;
- knowledge of basic laboratory hazards and safety;
- oral and written communication skills;
- interpersonal skills;
- ability to perform standard biomedical science, microbiological and biochemical examinations; ability to utilize computer software.

EXPERIENCE AND TRAINING General Experience:

Five (5) years of experience in a public health or clinical laboratory involving scientific work in the field of microbiology, biochemistry or molecular biology.

Substitution Allowed:

1. College training in the natural sciences may be substituted for the General Experience on the basis of fifteen (15) semester hours equaling one half (1/2) year of experience to a maximum of four (4) years for a Bachelor's degree.
2. A Master's degree in the natural sciences may be substituted for the General Experience.

3. Successful completion of the Connecticut Careers Trainee program in microbiology may be substituted for the General Experience.

5. An assessment of the adequacy of existing state facilities to perform testing for the state's shellfish industry.

Primary finding: The existing State facility in Milford is adequate to perform testing for the state's existing shellfish industry need.

The Bureau of Aquaculture & Laboratory at 190 Rogers Ave. in Milford has a twelve person staff comprised of two administrative positions, one research ship engineer, six environmental analysts, a shellfish pathologist, a Microbiologist 1 and a Microbiologist 2.

Laboratory capacity was limited by reduced staffing levels between 2009 and 2014, during which the Microbiologist 1 position remained vacant due to attrition. This vacancy placed a restriction on the daily analytical capacity of the laboratory, which was forced to prioritize testing for commercial shellfish growing areas over those areas associated with only recreational shellfishing activities. This administrative policy created a periodic capacity issue associated with the processing of ***recreational*** program samples.

The Department created and filled a microbiologist position in the Laboratory in January 2014 after the Administration and OPM supported the Department's critical funding and personnel action request.

The addition of this Microbiologist position has increased the daily processing capacity of the Laboratory staff, effectively doubling the capacity as compared to the five years prior to 2014.

Upon filling the position in January 2014, the addition of a Microbiologist 1 at the Milford laboratory has enabled the Department to eliminate policies which prioritized commercial samples above recreational areas, except as required during holidays or mandatory FDA inspections or evaluations which limits the total hours available for processing.

At no time during 2014 or 2015 was any eastern region shellfish commission or commercial grower informed that samples could not be collected because of processing capacity issues.

Table 3. Number and Types of Samples Analyzed by the Bureau of Aquaculture Laboratory in Milford

Year	Seawater Fecal Coliform	Phytoplankton Samples	Paralytic Shellfish Poison (PSP)	Shellfish Tissue Fecal Coliform	Total and Pathogenic Vibrio parahaemolyticus	Male Specific Coliphage
2013	6500	113	14	133	16	67
2014	6650	130	14	143	85	104
2015	6957	193	35	125	193	102

The Milford laboratory accepts water samples from Monday 8 am through Thursday at 1 pm, to allow for the 24 hour sample processing by the end of the business day of Friday. Samples may be collected as early as Sunday at 6 am, as samples must be processed within 30 hours of collection. Shellfish tissue samples are accepted until Wednesday at 1 pm, to allow for 48 hour sample processing. All laboratory receiving time limitations are based on the processing time required to complete testing within normal business hours, although exceptions may be made in case of emergency to staff the laboratory on the weekend.

In 2014, the Department made administrative changes in order to address state program deficiencies as cited in the FDA Regional Specialist's Shellfish Growing Area evaluation, while at the same time seeking to improve program efficiency and streamline administrative costs. The FY2013 FDA program evaluation had highlighted significant program deficiencies in Eastern Connecticut towns caused by insufficient growing area samples.

The administrative action taken in 2014 required the shellfish commissions of Stonington, Groton, Waterford, and East Lyme to transport water and shellfish samples to the Milford laboratory, rather than relying on a state employee to transport samples to the laboratory on their behalf, as had previously been the case. This change was made to eliminate a state employee providing what was essentially a courier service for samples, at a significant cost to the State in mileage and employee hours.

This ***transportation*** burden has been inaccurately characterized as a ***laboratory capacity*** issue. The insufficient collection of water samples for the previous three year period required commissions to make-up samples during 2015, which along with the collection of the regular routine program maintenance samples has been characterized as an ***increased sampling burden***.

The primary issue impacting the shellfish commissions who have raised this issue is that of the unwillingness to deliver samples to the Bureau laboratory in Milford from the towns located in the eastern end of Long Island Sound.

The collection of samples and transportation to the Milford laboratory requires a commitment of time and effort by local shellfish commissions. However, it is important to note that the towns of Greenwich, Stamford, Fairfield, Guilford, Madison, and Clinton have for many years collected and transported seawater and shellfish samples to the laboratory in support of their shellfish programs with no assistance from the State. These commissions have never had transportation provided to them by the Department of Agriculture.

The Milford Laboratory has the necessary physical capacity to handle water and shellfish tissue samples required to effectively manage both recreational and commercial shellfish industry needs. Additional sampling to support the expansion of both recreational and commercial programs ***beyond areas already in existence would not require additional space or equipment***, but because of the time commitment per test, additional laboratory staff would be needed.

The majority of commercial shellfish activity takes place in the western end of the sound. Commercial beds leased in State waters generate revenues that go into Connecticut's General Fund. Commercial shellfish leases in State waters in waters generate minimal revenues as compared to that generated from leases in waters west of the Connecticut River (Table 5). ***An important note: no funds are returned to the State for activities permitted within Town waters***. Commercial shellfish beds leased in Town waters and recreational shellfish permit fees provide funding to the municipalities for the management of these municipal shellfish programs. ***The Department of Agriculture performs the laboratory testing at no charge to municipal shellfish commissions.***

Table 5. Revenues generated from commercial leases in State waters.

	State Acres Leased	Dollars Generated Annually
East of the Connecticut River	Groton 87.3 Stonington 683.70	$9,247.51

West of the Connecticut River	49,553.79	$845,036.55

6.0 Tthe volume of testing that could occur at a facility established east of the Connecticut River

The volume of testing that could be performed at a newly established facility east of the Connecticut River is dependent upon adequate facilities, staffing, and procedures as outlined in this report and determined to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.

Depending on where such a facility was located, municipalities from Westbrook to Stonington would conceivably find it more convenient to transport samples to a new laboratory. Based on the minimum volume of samples required to maintain compliance with the NSSP minimum sampling requirements, the number of water samples that would need to be processed per year is 1335 for towns from Westbrook to Stonington. Additional post-rainfall seawater and tissue samples required for and reopening areas closed after rainfall or sewage events would require an additional testing burden of an unpredictable volume of samples per year.

Only routine seawater and shellfish tissue testing for fecal coliform bacteria would be processed at an additional backup facility. More complex analytical methods required for MSC, Vibrio, or PSP toxin analysis would still be performed at the Milford facility.

The report must also (1) identify any existing privately owned facilities, state resources, or state facilities that could adequately and appropriately serve as a testing laboratory east of the Connecticut River and (2) include a cost-benefit analysis on modifying existing state resources or facilities to perform the testing.

Primary finding: The Bureau does not have the architectural, engineering, or building code background necessary to assess the adequacy of the 676 identified existing state resources or state facilities, nor the capacity to conduct a detailed cost-benefit analysis on modifying existing resources. Based on a simple cost-benefit analysis of staffing and equipping a new laboratory versus meeting demands through the Milford laboratory, the most cost-effective way to increase services provided to the commissions would be to address courier services to and from the Milford laboratory from the shellfish commissions east of the Connecticut River.

The Bureau of Aquaculture & Laboratory has a 12 person staff. The administrative and technical services required in support of shellfish program workload necessarily limit the time available to perform a complex assessment. It was determined that assessing all existing privately owned, state resources, or state facilities located East of the CT River was not possible within the time-frame provided to us for performing such as assessment given our program responsibilities and given the fact that we do not have this expertise available to us within our small staff.

Exhibit 8 is a list of state owned buildings, leased locations, and Payment in Lieu of Taxes (PILOT) parcels in the fifteen municipalities making up southeastern Connecticut shoreline area. The information was obtained in a spreadsheet from the Office of Policy and Management (OPM). The spreadsheet line items consist of 524 parcels under the PILOT Program, 13 leased buildings/locations, and 136 state owned buildings. An assessment of the adequacy of these 673 identified facilities to perform testing for the State's shellfish

industry would have required significant staff time and diversion of the Bureau's limited resources. The diversion of that individual from our required laboratory work would result in an inability of our laboratory to meet our minimum analytical requirements.

Within our laboratory one individual has the qualifications to determine the adequacy of a laboratory facility in the performance of mandatory NSSP MO analytical testing. However, that individual is not an architect, engineer, or building code planner and does not have the experience to effectively assess a structure for adequacy and appropriateness.

The Department was also charged with evaluating privately owned facilities. Historically, there have been private laboratories who were certified through the FDA to process the seawater samples for fecal coliform analysis, however the high cost per sample price discouraged shellfish commissions from using these private laboratories and the lack of sufficient business forced the private laboratories to drop the costly certification and analysis. It is unknown at this time whether or not any private laboratories would be interested in going through the certification process and cost of adopting additional analytical methods.

(2) include a cost-benefit analysis on modifying existing state resources or facilities to perform the testing

The University of Connecticut reported to the committee last session that the Avery Point Campus laboratory was at capacity and a new facility would need to be constructed for a shellfish regulatory laboratory and is included in the report as Exhibit 7. The preliminary cost estimates provided by the University at that time were not based on the required standards as outlined in this report under sections 1, 2, and 3, however the construction costs indicated in that report were used as an estimate for construction costs for a new laboratory.

The Bureau does not have engineering or technical staff to undertake a cost-benefit analysis on modifying existing state resources or facilities to perform the testing. Our expertise is in the management, administration, and operation of the laboratory as necessary for the support of the State's shellfish program.

A very simple cost-benefit analysis for three scenarios was constructed with regard to the required staffing and equipping of a new laboratory.

Scenario 1: Provide paid courier to transport samples from the eastern towns to the Milford laboratory. The towns of East Lyme, Waterford, Groton and Stonington could potentially raise their commercial and recreational permit fees, and use the additional funding to hire a paid courier to transport samples to the Milford laboratory. Having the commissions hire a paid courier to eliminate the transportation burden is the most cost-effective option for the state, and is how other shellfish commissions operate.

Scenario 2: Building, equipping and staffing a new shellfish laboratory east of the Connecticut River in compliance with the standards required by the National Shellfish Sanitation Program, and as overseen by FDA. This scenario is the most expensive of the three, with an initial start-up investment of at least $846,000 and annual expenditures of $278,000. The initial construction costs associated with a new laboratory depends on many factors. An estimate of $350,000 was provided using the UCONN estimate for a modular building and associated costs, but this could be significantly higher depending on the facility.

In order to staff a new laboratory, two new Microbiologist 1 positions would be required, with an annual cost for salary and fringe benefits of $112,000 per position. Significant costs would also be associated with the commitment of supervisory Microbiologist staff to oversee the development and training of laboratory staff

at the new lab, with a cost of $20,000 per year. This staff investment would also pull Milford staff away from processing duties and would place an additional limitation on the volume of samples able to be processed in Milford.

Scenario 3: Expanding services at the existing shellfish laboratory in Milford. If the goal is to increase the number of samples able to be processed at the Milford laboratory following rainfall events, which present the greatest capacity burden, adding staff to the existing DABA laboratory is the most cost-effective investment. There would be no start-up costs associated with this option, and the annual costs associated with Scenario 3 would be $260,000 dollars. [SCF1]

The DABA cost per sample was calculated by using current prices from our scientific vendor Fisher Scientific. This price includes consumable supplies for routine fecal coliform analysis using the mTEC method and time of one individual in the laboratory processing the sample. The price is $3.41 per sample. The price does not reflect existing infrastructure costs such as autoclave maintenance, cost of water purification system, energy costs and initial cost for equipment.

In order to process an additional 100 samples per day following a rainfall event, consumable supplies and processing staff would have a cost of $341.00 or 1364.00 per rain event. If we use an estimate of twelve rainfall events per year, then the total annual cost is $16,368 in supplies. This additional expenditure would allow the laboratory to process an additional 400 samples per rainfall event. The laboratory would require an additional microbiologist at $112,000.00 for salary and fringe benefits.

Adding an Environmental Analyst staff member would provide an even greater benefit by enabling the DABA to expand opportunities for commercial and recreational growing areas. The creation of an additional field analyst position would allow DABA to conduct special studies to evaluate the potential for upgrades to growing area classifications. The cost of adding an Environmental Analyst staff member would be $115,000 for salary and fringe benefits.

Scenario 3 also includes a line item for a courier with an annual cost of $16,000.

Table Six below provides the cost analysis for these three scenarios.

Table 6. Cost analysis for three scenarios for expanding access to laboratory services for shellfish programs.

	Scenario 1: Provide Courier from East to Milford Lab	**Scenario 2: New Shellfish Lab East of CT River**	**Scenario 3: Expand Services at Existing DABA Lab in Milford**
Construction		$350,000 (*UCONN estimate*)	$0.00
Equipment		$218,603	$0.00
Micro 1 position #1		$112,000 ($47,000 + $65,000 fringe)	$112,000 ($47,000 + $65,000 fringe)
Micro 1 position #2		$112,000 ($47,000 + $65,000 fringe)	$0.00
Environmental Analyst 1		$0.00	$115,000 ($49,000 + $66,000 fringe)
Courier	$16,000	$0.00	$16,000

	Scenario 1: Provide Courier from East to Milford Lab	Scenario 2: New Shellfish Lab East of CT River	Scenario 3: Expand Services at Existing DABA Lab in Milford
Supplies		$10,000	$16,368
DABA Support		$20,000	$0.00
Equipment Service Contracts		$8000.00	$0.00
Total Cost: Start-up Year 1		**$834,603**	**$0.00**
Total Cost: Annual	**$16,000**	**$262,000**	**$259,368**

Summary of Report Findings:

1. The National Shellfish Sanitation Program *Guide for the Control of Molluscan Shellfish* determines the microbiological methods that a laboratory may use to process shellfish meats: APHA decimal dilution – MPN for fecal coliform indicator in seawater and shellfish and the mTEC method for fecal coliform indicator in seawater.
2. The NSSP *Guide for the Control of Molluscan Shellfish* describes in detail the procedures that must be followed in order to designate a laboratory as an "NSSP Laboratory" for the purpose of providing analytical support to a state shellfish sanitation program. The DABA in its role as the State Shellfish Authority must ensure compliance with Chapter III of the current NSSP *Guide for the Control of Molluscan Shellfish* as summarized below:
   - All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP;
   - The NSSP Laboratory must have qualified, adequately trained staff with appropriate, calibrated equipment and workspace sufficient to conduct the numbers and types of daily/weekly/monthly analyses anticipated;
   - The Authority shall ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results;
   - Any shellfish laboratory DABA laboratory uses the following approved NSSP microbiological testing methods; APHA Decimal dilution – MPN for fecal coliform indicator in seawater and shellfish and the mTEC method for fecal coliform indicator in sewage and seawater.
3. The equipment list found in Exhibit 5 will enable a laboratory to process shellfish meats and seawaters for the following NSSP microbiological testing methods; APHA decimal dilution – MPN for fecal coliform indicator in seawater and shellfish and the mTEC method for fecal coliform indicator in seawater.
   Based on the most current equipment quotes provided by the approved State of Connecticut vendor Fisher Scientific, the total cost to equip a newly established laboratory is $218,603.
   A laboratory facility will need a minimum of 1500 square feet. The space will comprise 300 square feet of office administrative area and 1200 square feet of laboratory space consisting of benches, counters, work area, and sinks. Within the 1200 laboratory space, a minimum of 300 square feet must be a dedicated room constructed for the autoclave and glass washing machine, which generate significant amounts of heat. These laboratory space requirements do not include restroom or break facilities which would require additional square footage.

4. The minimum qualifications required by the State of Connecticut Department of Administrative Services for a Microbiologist 1 are found in Exhibit 6 State of Connecticut Department of Administrative Services Exam Announcement Microbiologist I.
5. The existing State facility in Milford is adequate to perform testing for the state's shellfish industry. Additional testing services could be provided by increasing staffing levels at the Bureau in order to provide courier service to the Bureau from the Eastern region, adding an additional Microbiologist 1 position to provide additional analytical capacity in the laboratory, and adding an Environmental Analyst 1 position to provide for additional field sample collection and increased monitoring of pollution sources such as sewage treatment plants with the goal of expanding opportunities for upgrading additional grounds for commercial and recreational shellfishing activities.
6. The volume of testing that could be performed at a newly established facility east of the Connecticut River is dependent upon adequate facilities, staffing, and procedures as outlined in this report and determined to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP.

   Depending on where such a facility was located, municipalities from Westbrook to Stonington would conceivably find it more convenient to transport samples to a new laboratory. Based on the minimum volume of samples required to maintain compliance with the NSSP minimum sampling requirements, the number of water samples that would need to be processed per year is 1335 for towns from Westbrook to Stonington. Additional post-rainfall seawater and tissue samples required for and reopening areas closed after rainfall or sewage events would require an additional testing burden of an unpredictable volume of samples per year.
7. The Bureau does not have the architectural, engineering, or building code background necessary to assess the adequacy of the 676 identified existing state resources or state facilities, nor the capacity to conduct a detailed cost-benefit analysis on modifying existing resources.

   Based on a simple cost-benefit analysis of staffing and equipping a new laboratory versus expanding services at the Milford laboratory, the most cost-effective way to increase services provided to the commissions, while expanding opportunity to upgrade additional shellfishing areas would be to increase staffing at the Milford laboratory and provide a paid courier to transport samples for the eastern shellfish commissions.

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[i] [ISSC] Interstate Shellfish Sanitation Conference. 2013. National Shellfish Sanitation Program: Guide for the Control of Molluscan Shellfish. US Department of Health and Human Services Public Health Service Food and Drug Administration.